Liver and Intestinal Organ Transplantation Committee Update
Fall 2011

Kim Olthoff, MD, Chair
David Mulligan, MD, Vice-chair
Ken Washburn, MD, Immediate Past Chair

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Items to be Submitted to the Board, November 2011 (1 of 3)

Proposal for Improved Imaging Criteria for HCC Exceptions

- Public Comments: 69% with an opinion (n=26) in support.
- Regions 1, 2, 3, 5, 6, 7, 8,9, 10, 11 in support
- Patient Affairs Committee, ASTS and NATCO in support
- Compromise made with LI-RAD Group

Items to be Submitted to the Board, November 2011 (2 of 3)

Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates

- Public Comments: 83% with an opinion (n=18) in support
- Regions 1,4,5,6, and 11 in support; Region 2 supported with amendments.
- Organ Availability and Pediatric Committees supported; Patient Affairs Committee did not
- ASTS and NATCO indicated their support

Items to be Submitted to the Board, November 2011 (3 of 3)

Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation

- Public Comments: 100% with an opinion (n=17) in support
- All Regions in support
- OPO, Patient Affairs, and Transplant Coordinators Committees in support; Pediatric Committee did not support
- ASTS and NATCO in support

Other Committee Initiatives

- MELD Enhancements Subcommittee
  - Possible addition of sodium to MELD score
  - Possible exception for Recipients of DCD Livers
- Liver Utilization Subcommittee
  - Reducing discards
  - “Facilitated Placement”
- Status 1 Review Subcommittee

Questions?

Liver and Intestinal Organ Transplantation Committee

Proposals for Public Comment Fall 2011

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Two Proposals

- Extend Share 15 Regional to Share 15 National
- Share 35 Regional

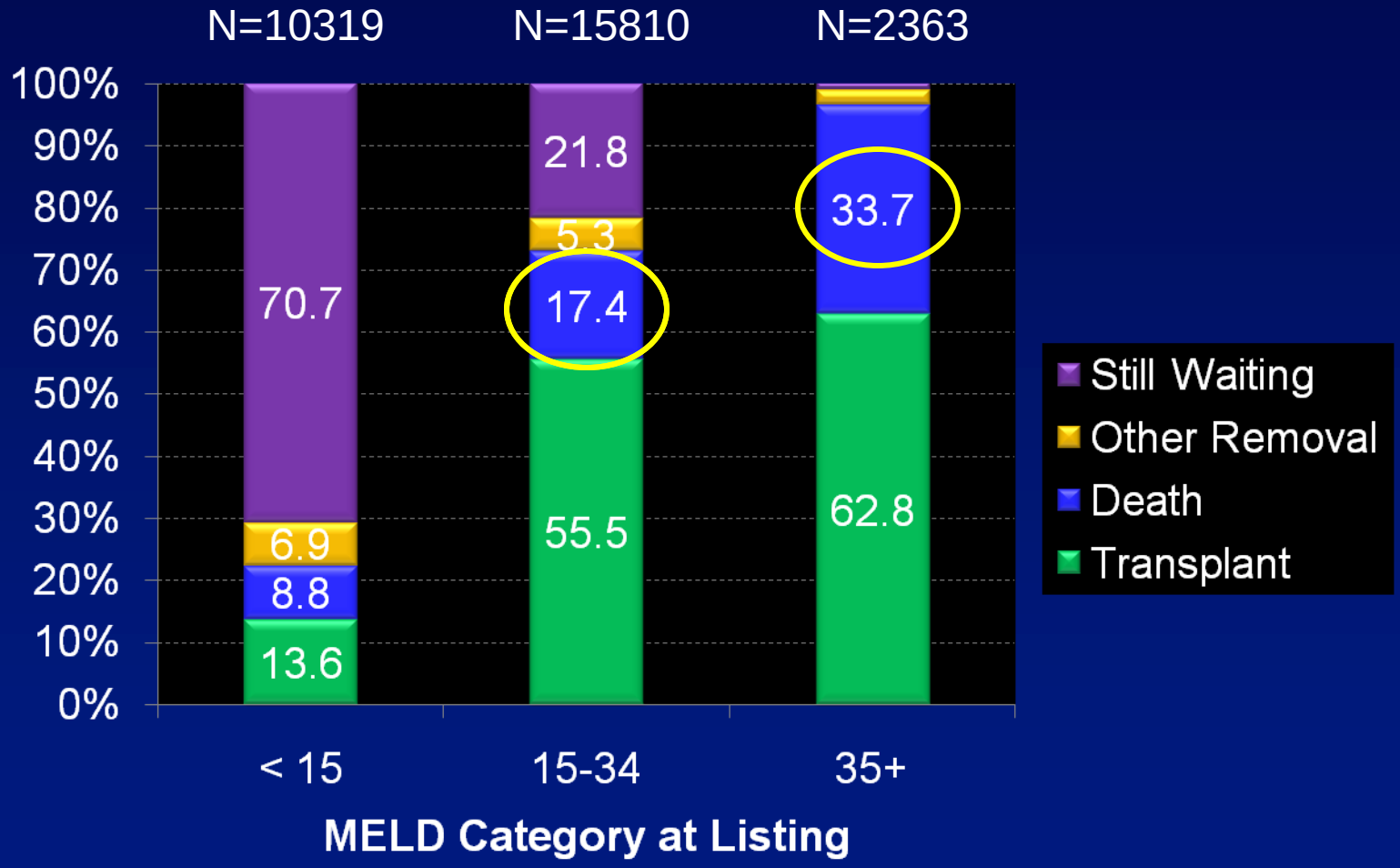
- Shared Problem Statement
- Both Developed 2009-2011

PROBLEM STATEMENT / BACKGROUND

Problem Statement

- Despite improvements in liver allocation and distribution, waitlist mortality remains high for patients with higher MELD scores
- Significant disparity exists between OPOs and regions with regard to mean MELD at transplant and waitlist mortality
- How can we direct livers to most in need?

Competing Risk Liver Waiting List Outcome Probabilities at 1-Year Candidates Added 2007-2010



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*Status 1A/1B, and candidates with exceptions excluded

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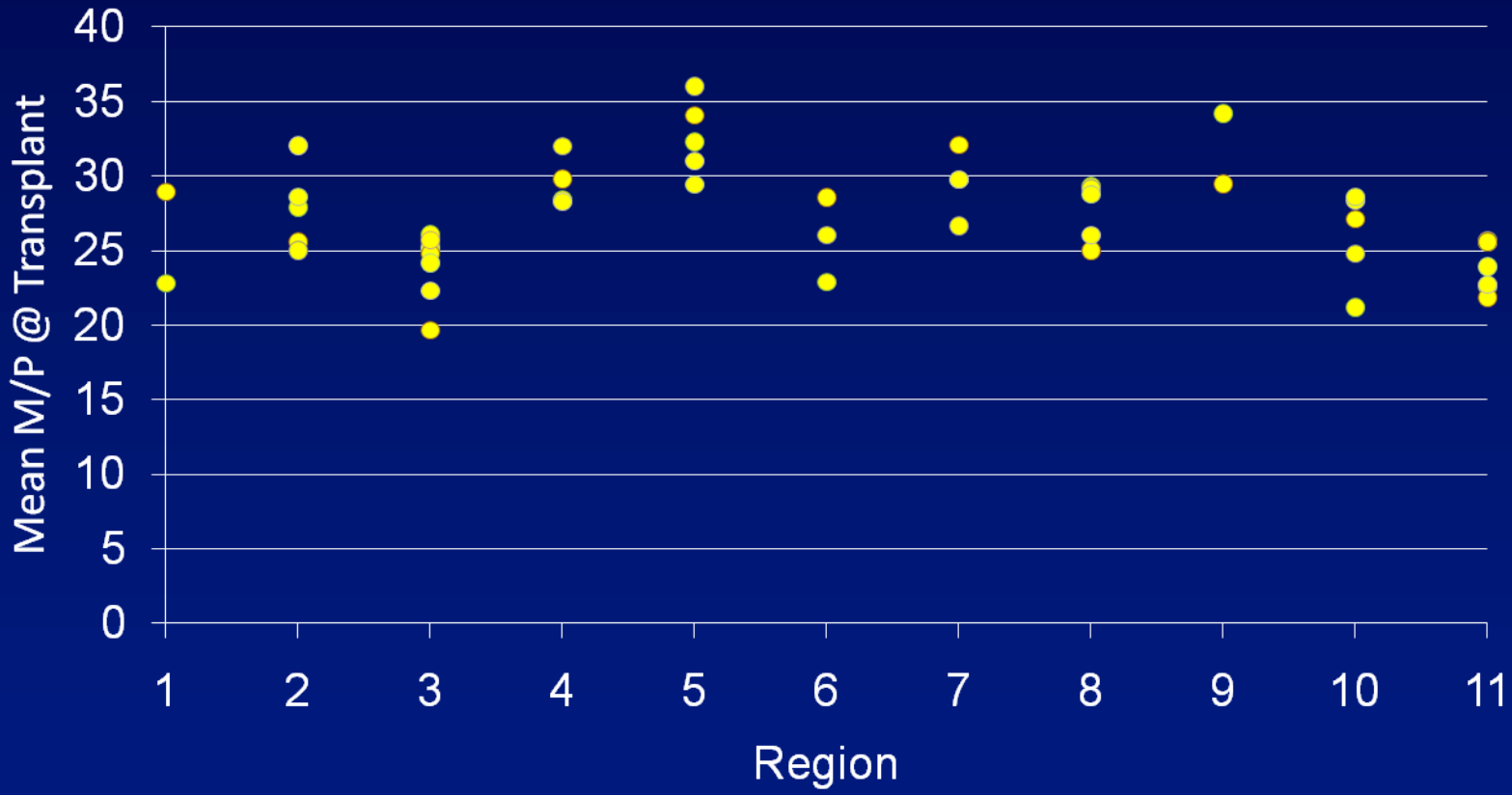
Mean Match MELD @ Transplant*
Deceased Donor Liver Transplants, 2010
by DSA within Region



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*Adults only, No Exceptions. Some DSAs may overlap

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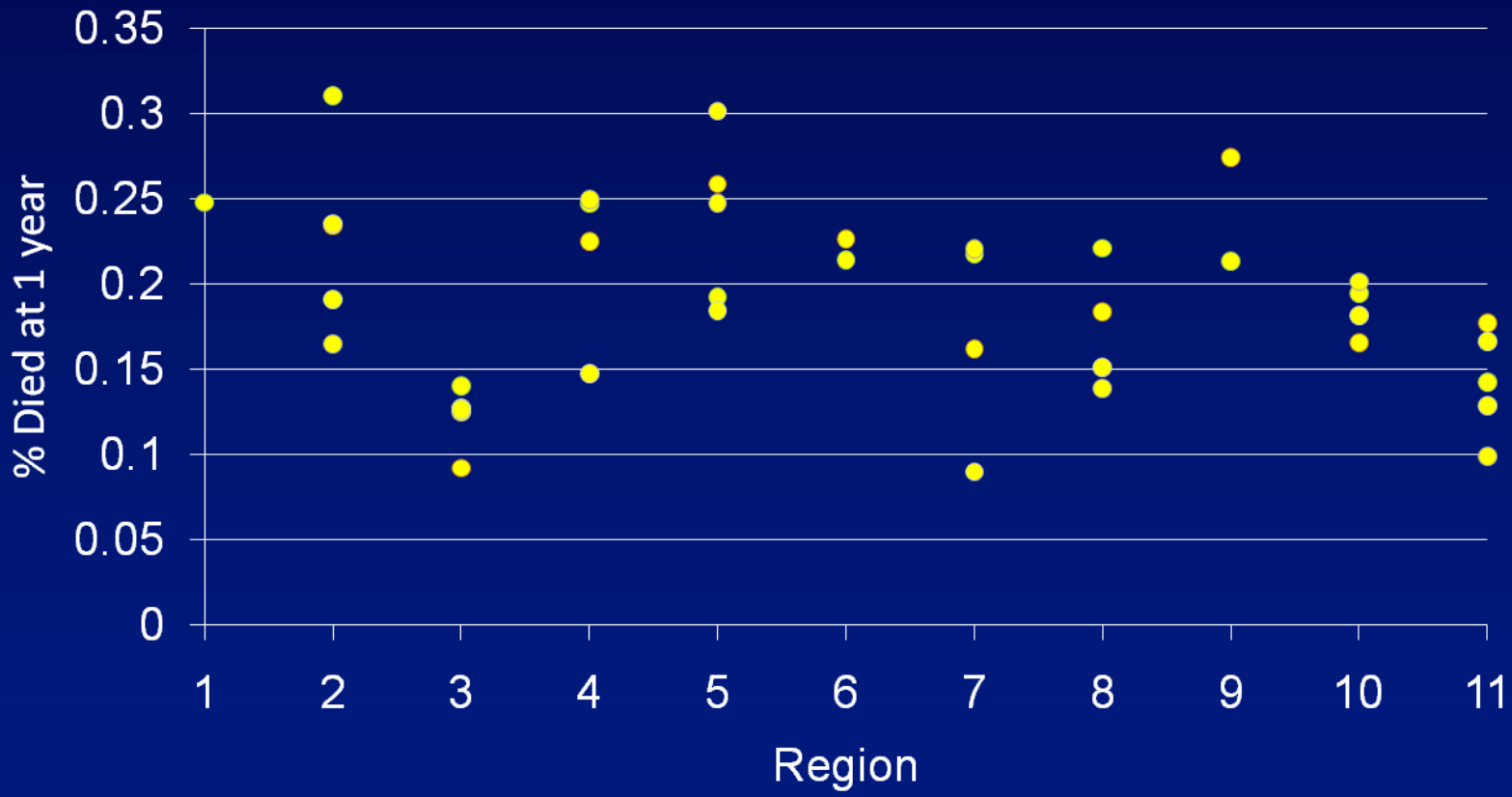
Death Rates* @ 365 Days
Candidates Listed for a DD Liver Transplant
1/1/2008-12/31/09
By DSA within Region



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*Adults only, No Exceptions, Initial MELD>=15, Candidates with an Initial Status of 1A/1B Excluded, DSAs with fewer than 10 events excluded

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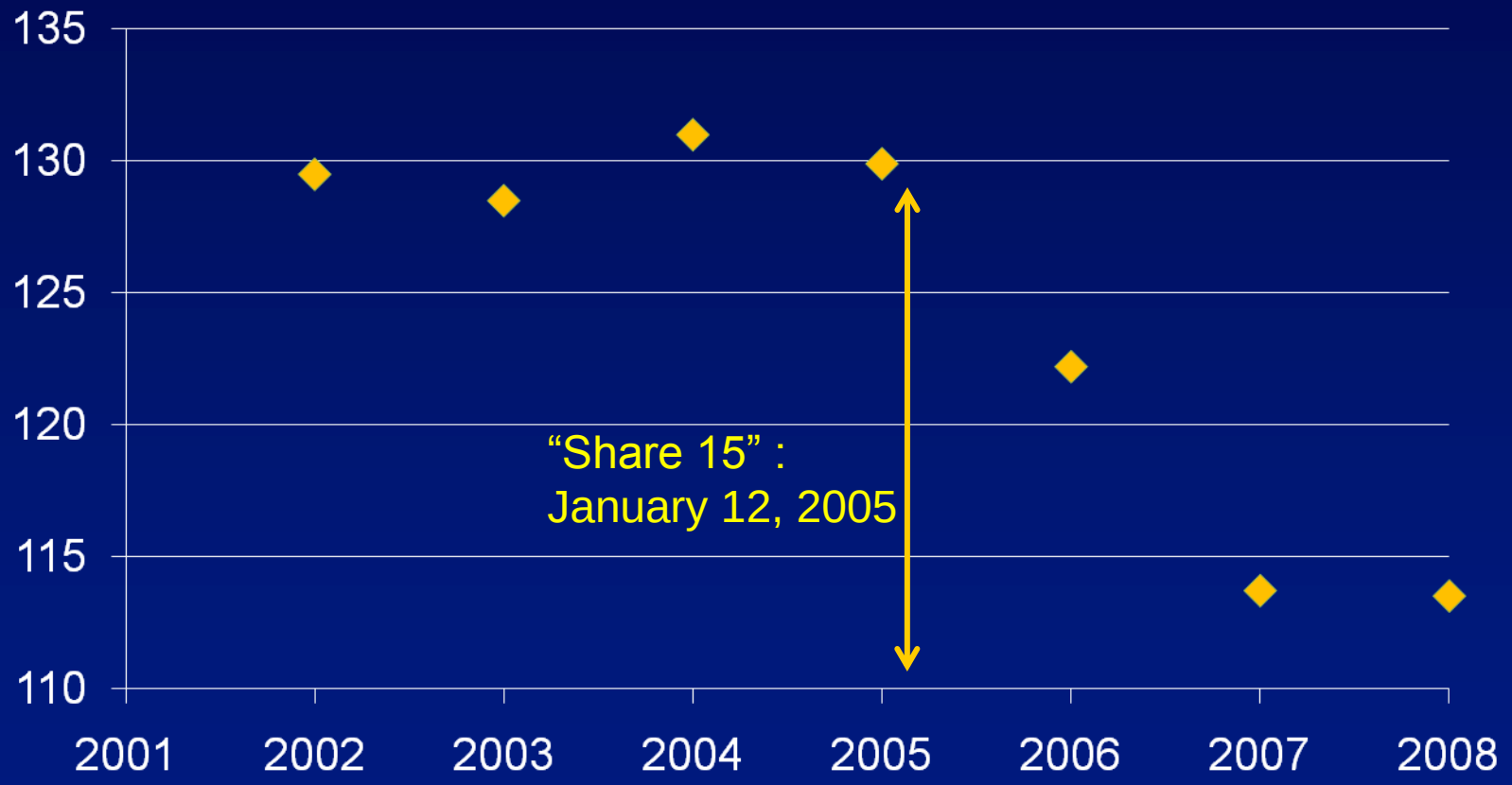
Potential Solutions

- Modeling has shown that waitlist mortality can be reduced through broader distribution
  - Share 15 Regional proved effective
  - Currently have regional distribution for Status 1A/1Bs
  - Other methods possible (concentric circles used in thoracic allocation)

Annual Death Rates Per 1,000 Patient-Years at Risk (2002-2008)



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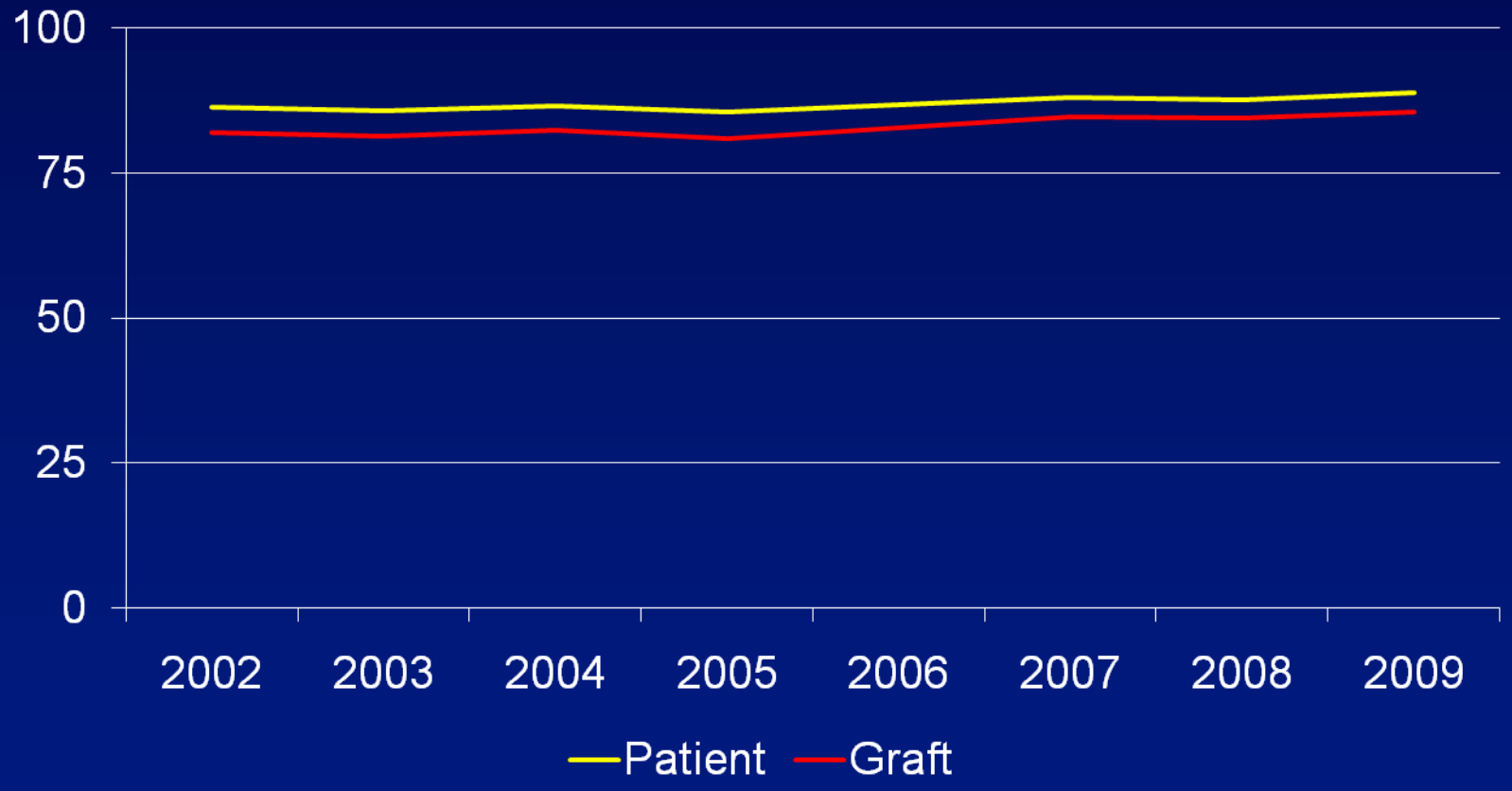
1-Year Post-Transplant Graft and Patient Survival Rates
Organ: Deceased Donor Liver



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Guidance: OPTN Final Rule

§ 121.8(b) Allocation performance goals. Allocation policies shall be designed to achieve equitable allocation of organs among patients consistent with paragraph (a) of this section through the following performance goals:

…

(3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency

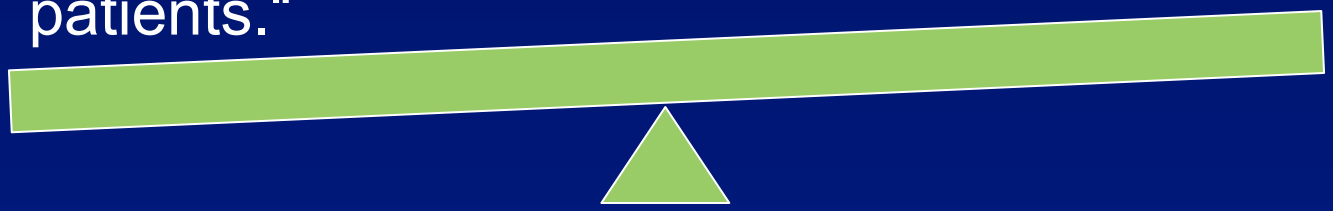
Liver Committee Charge

The goal of the Committee's work is to develop evidence-based policies aimed at reducing the burden of liver disease in transplant patients (candidates and recipients), increasing liver utilization, improving access to liver transplantation, and improving the health outcomes of liver transplant recipients.

Messages from Transplant Community

“Broader sharing is reasonable for critically ill patients.“

“Make small incremental Steps.”



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Options Considered

- Full Regional Sharing (2009)
- Concentric Circles
- Extension of Share 15 Regional
- Tiered Regional Sharing
- Net Transplant Benefit (with and w/o broader distribution)

Policy Development History

- Proposal for Regional Sharing (February 2009)
- Request for Forum (June 2009)
- RFI and Survey (December 2009)
- Forum in Atlanta (April 2010)
- Board directed Committee to develop recommendations to reduce geographic disparities in waitlist mortality (June 2010)
- Concept Paper/Survey (December 2010)
- Presentations at AASLD, ASTS Winter Symposium, ATC (2010 and 2011)

Options Considered

- Full Regional Sharing – strong opposition
- Concentric Circles – mixed support
- Extension of Share 15 Regional – strong support
- Tiered Regional Sharing – strong support for some level (29, 32, 35, other)
- Net Transplant Benefit – mixed support

Two Options Being Proposed

- Extension of Regional Share 15 => Share 15 National

- Share 35 Regional
  - Candidates with MELD/PELD scores of 35 and higher

- Could be combined if both approved

Share 15 National*

- Regional Status 1A
- Regional Status 1B
- Local MELD/PELD>=15
- Regional MELD/PELD>=15
- National Status 1A
- National Status 1B
- National MELD/PELD>=15
- Local MELD/PELD<15
- Regional MELD/PELD<15
- National MELD/PELD<15

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* Adult Donors Only

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Share 35 Regional

1. Regional Status 1A
2. Regional Status 1B
3. *Local and Regional M/P >=35*
4. Local M/P 15-34
5. Regional M/P 15-34
6. Local M/P < 15
7. Regional M/P <15
8. National Status 1A
9. National Status 1B
10. National M/P ≥ 15
11. National M/P < 15

- 3.1 Local M/P 40
- 3.2 Regional 40
- 3.3 Local M/P 39
- 3.4 Regional M/P 39
- 3.5 Local M/P 38
- 3.6 Regional M/P 38
- 3.7 Local M/P 37
- 3.8 Regional M/P 37
- 3.9 Local M/P 36
- 3.10 Regional M/P 36
- 3.11 Local M/P 35
- 3.12 Regional M/P 35

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* Adult Donors Only

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Share 35 Regional Combined with Share 15 National*

1. Regional Status 1A
2. Regional Status 1B
3. *Local and Regional M/P >=35*
4. Local M/P 15-34
5. Regional M/P 15-34
6. National Status 1A
7. National Status 1B
8. National M/P ≥ 15
9. Local M/P < 15
10. Regional M/P <15
11. National M/P < 15

- 3.1 Local M/P 40
- 3.2 Regional 40
- 3.3 Local M/P 39
- 3.4 Regional M/P 39
- 3.5 Local M/P 38
- 3.6 Regional M/P 38
- 3.7 Local M/P 37
- 3.8 Regional M/P 37
- 3.9 Local M/P 36
- 3.10 Regional M/P 36
- 3.11 Local M/P 35
- 3.12 Regional M/P 35

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* Adult Donors Only

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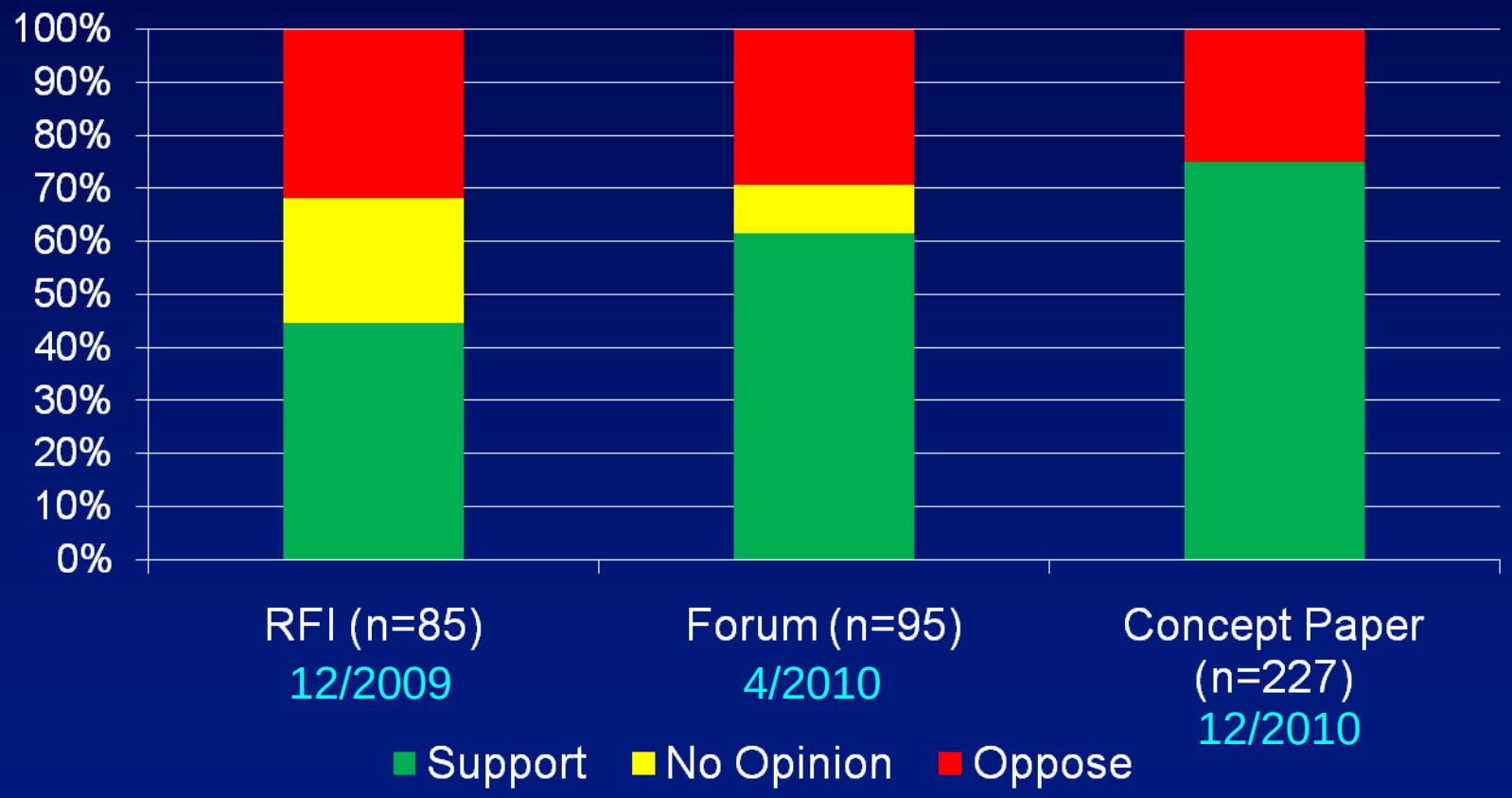
COLLABORATION/EVIDENCE OF COMMUNITY SUPPORT

Share 15 National



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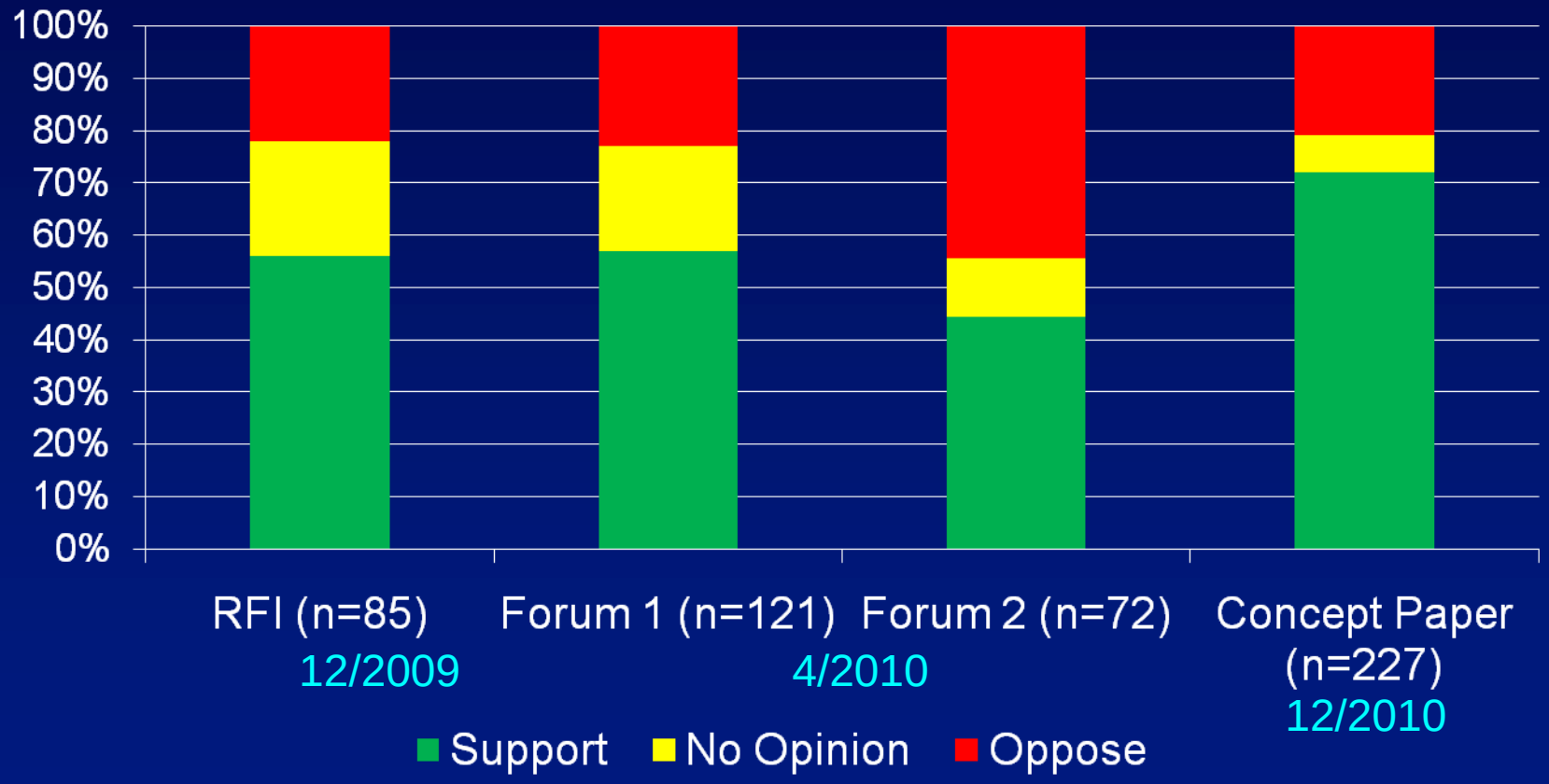
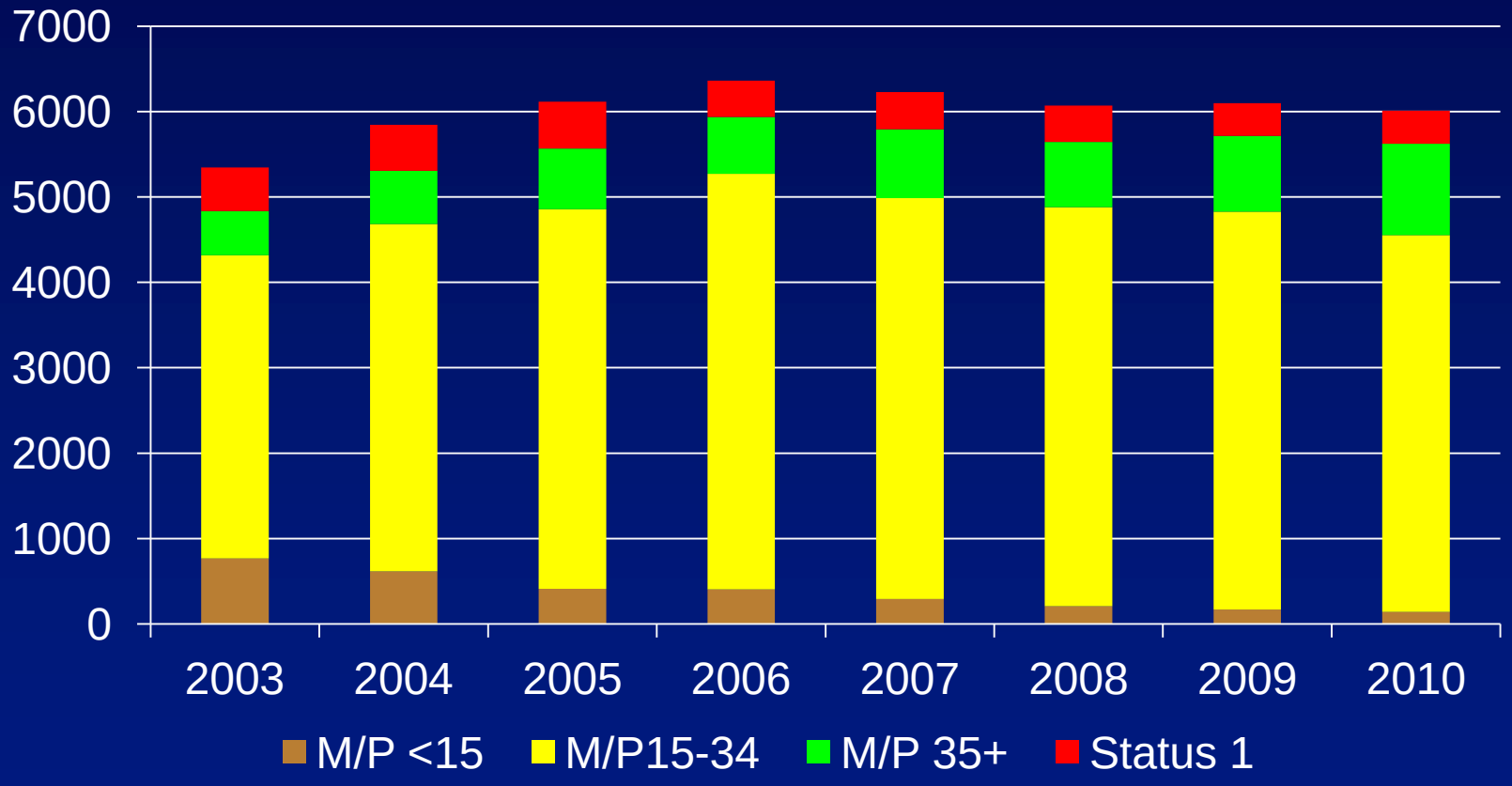
Regional Sharing for Candidates with High MELD/PELD Scores



EVIDENCE / MODELING

Deceased Donor Liver Transplants, 2003-2010 By Status/Score



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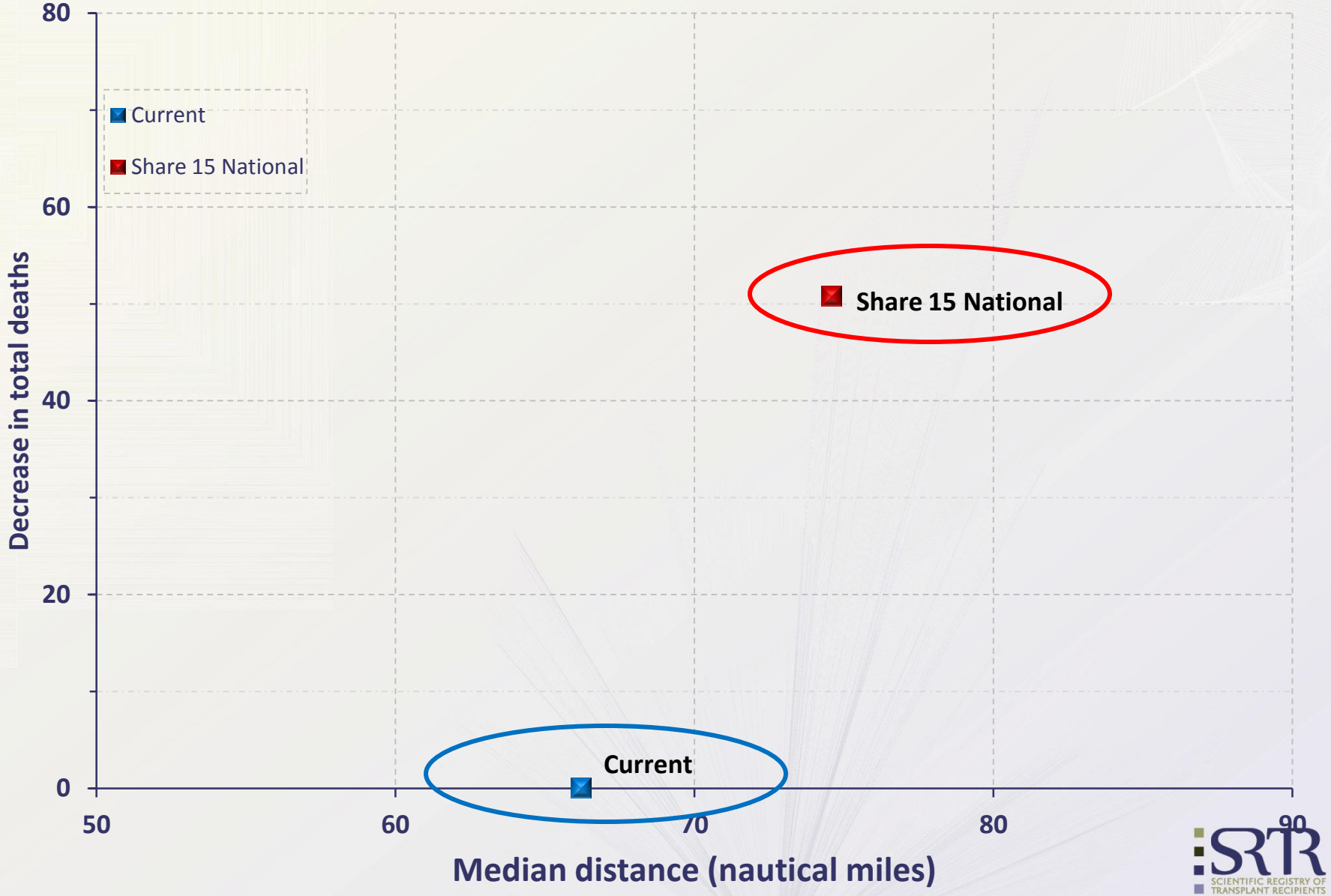
Supporting Evidence: Share 15N

- Reduced waitlist deaths since Share 15 regional implemented
- Demonstrated in all 11 regions since 1/12/2005

Decrease in Total Deaths vs. Percent Shared

Decrease in Total Deaths vs. Median Distance



SRTR
SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

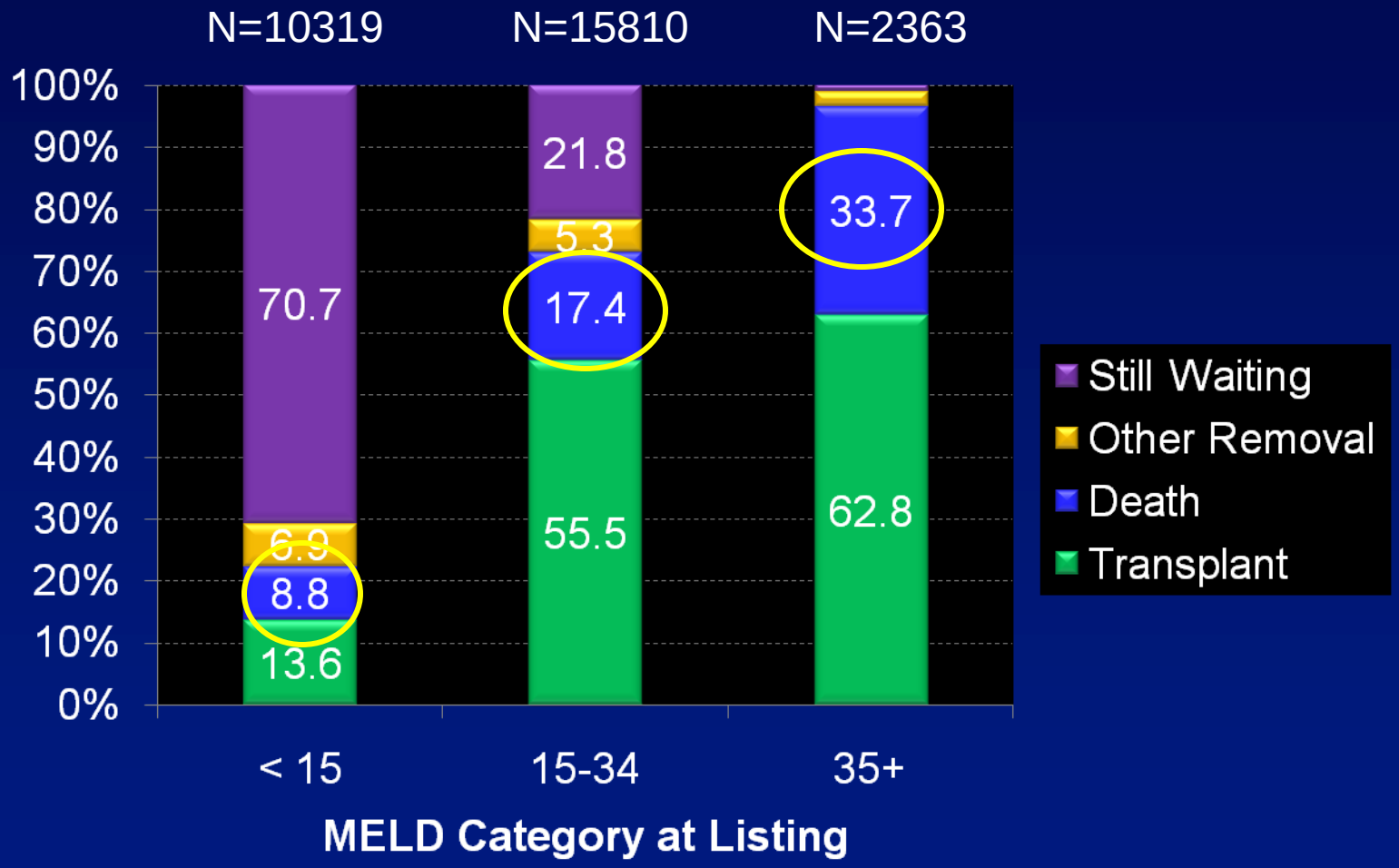
Supporting Evidence: Share 35R

- Mortality for MELD >=35:

  Sharma et al AJT 2009 “There was no difference in WL mortality of patients with MELD 36-39 and Status 1”

  - Full Regional Sharing for Status 1A/Bs implemented 12/15/2010
  - Local, then Regional Sharing for Status 1 since 1999

Competing Risk Liver Waiting List Outcome Probabilities at 1-Year Candidates Added 2007-2010



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*Status 1A/1B, and candidates with exceptions excluded

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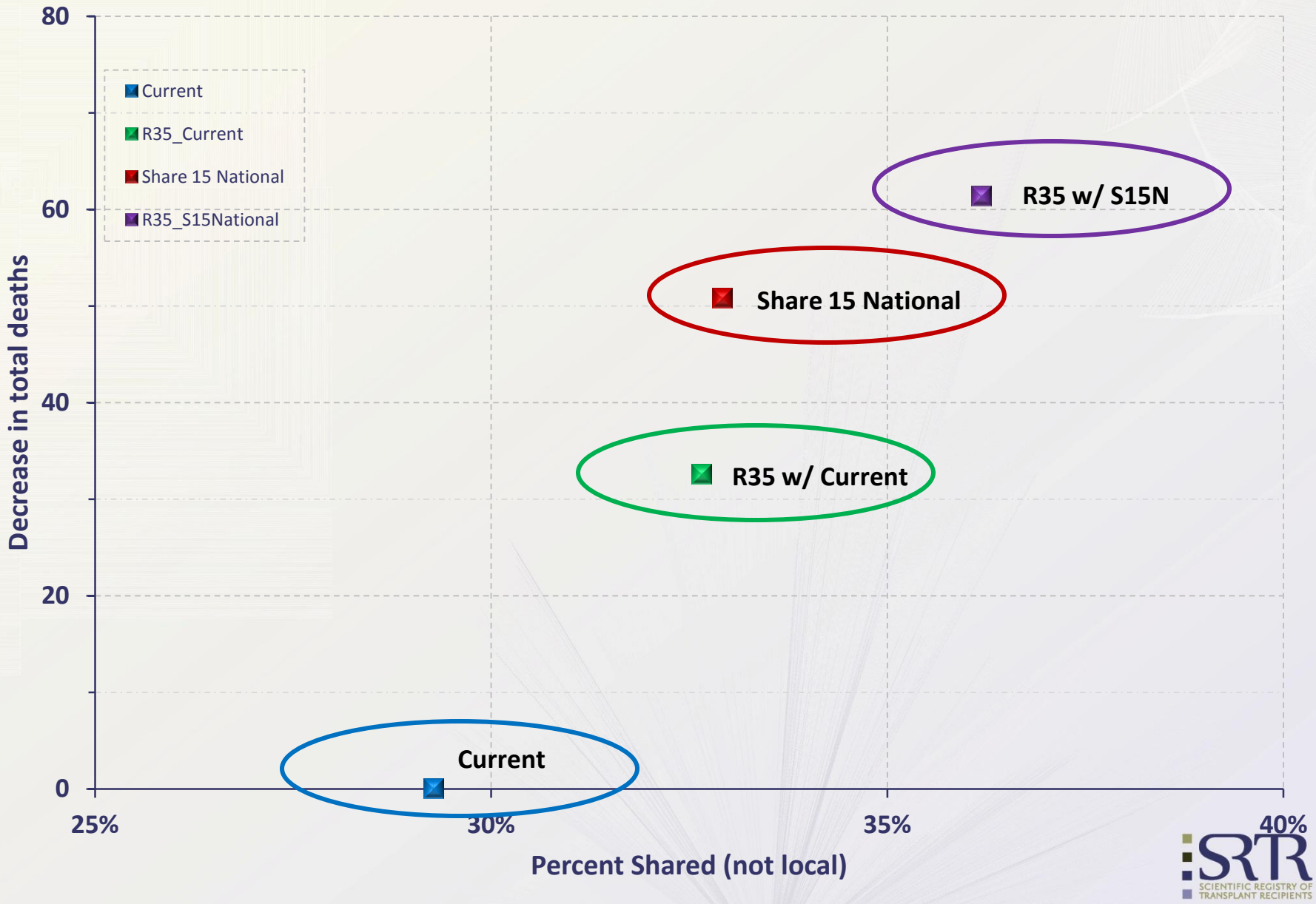
Decrease in Total Deaths vs. Percent Shared



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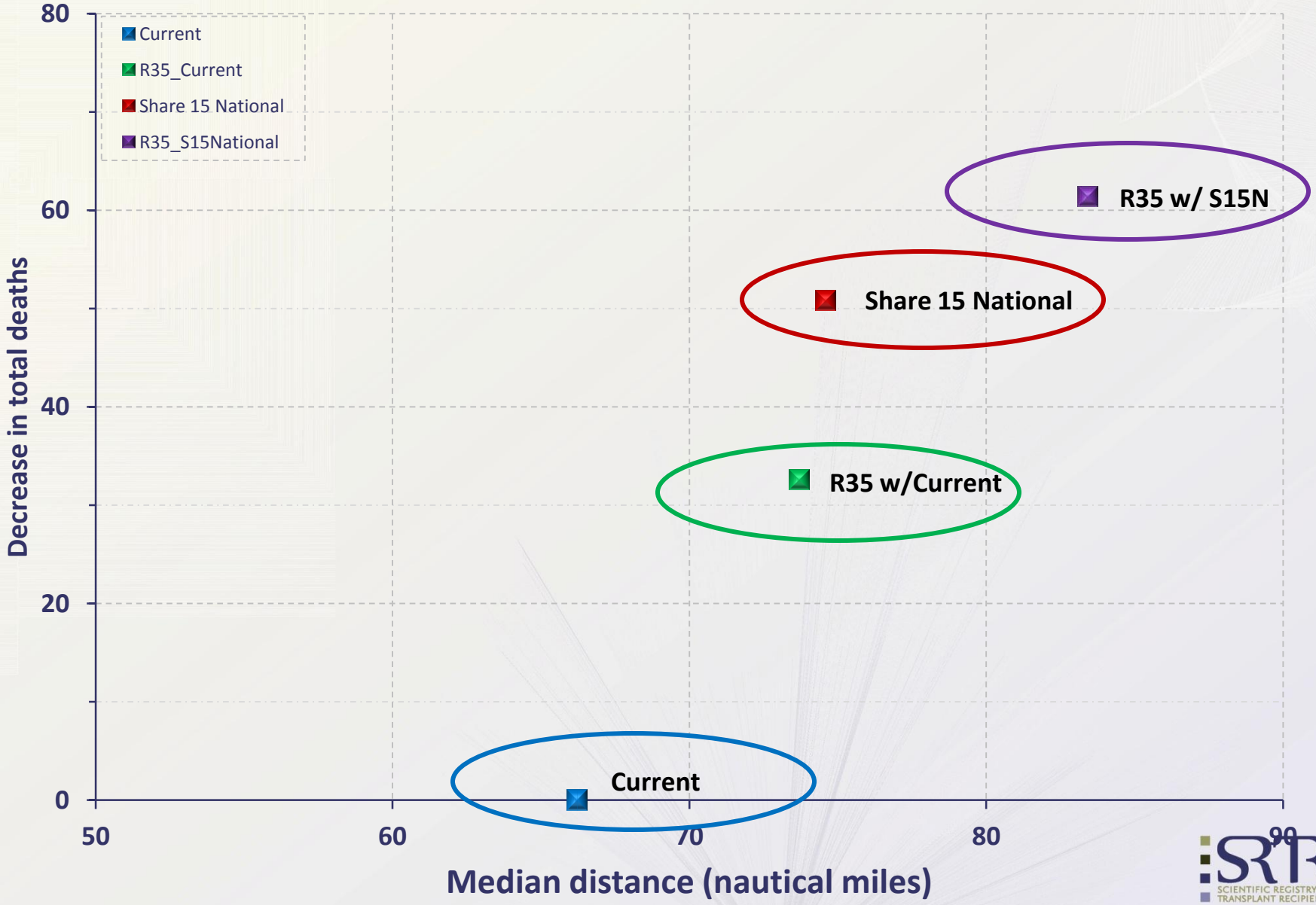
SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Decrease in Total Deaths vs. Median Distance



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SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Potential Concerns

- Some candidates with MELD/PELD scores less than 15 could be disadvantaged (S15)
- Organs “criss-crossing” for similar patients
- Longer distance traveled, increased CIT
- Lengthier stay or poorer post-tx outcomes due to transplanting sicker patients (S35)
- Increased cost (travel, patient care)
- Impact on local donation
- Minimal impact – affects small amount of patients
- Why not share 29 or 32? (S35)

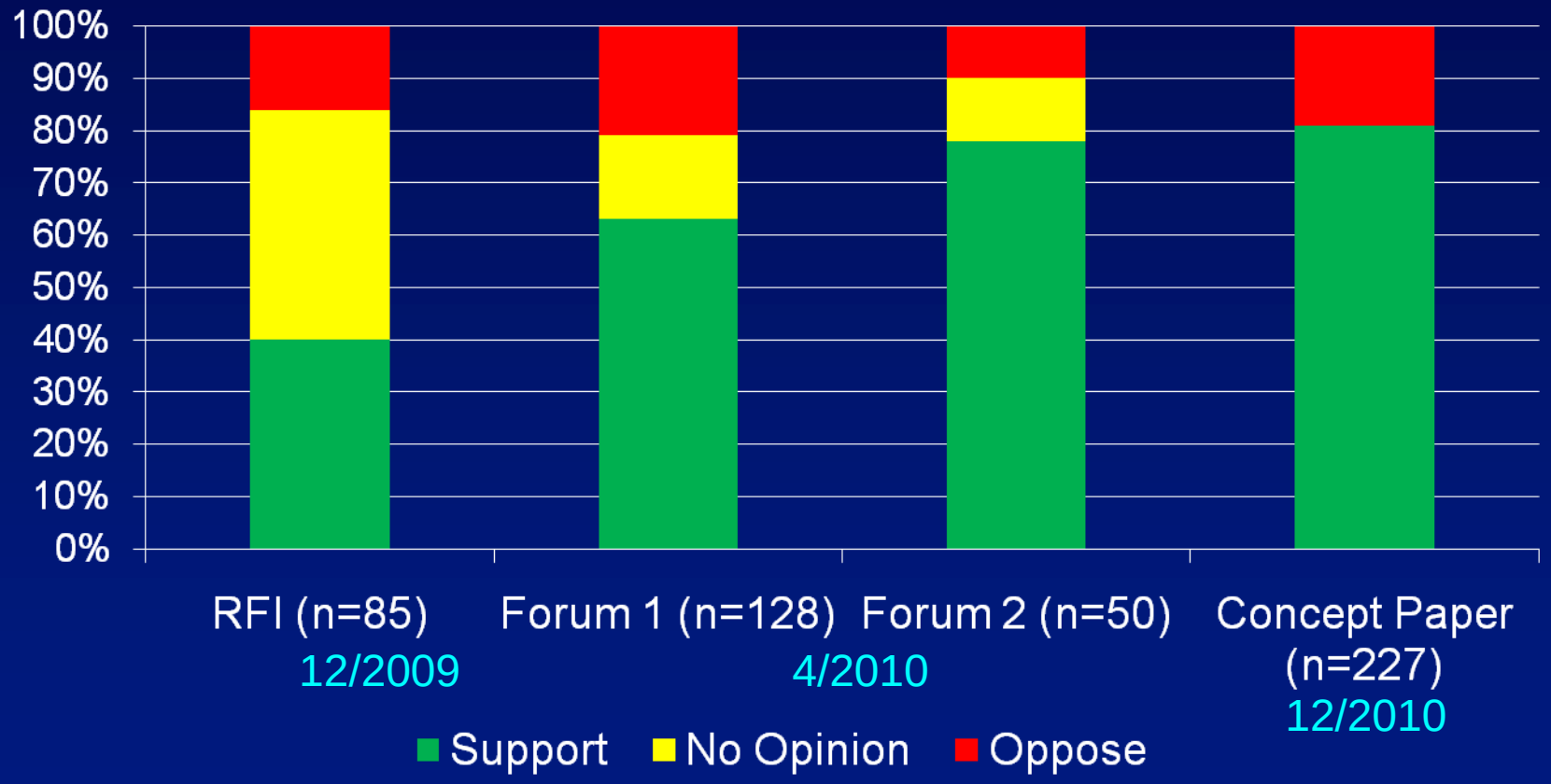
Impact on Candidates with Low MELD scores

- Survey showed mixed concerns (47%)
- Most concerned about hyponatremic candidates
- Committee considering MELD-Na
  - Would mitigate potential negative impact

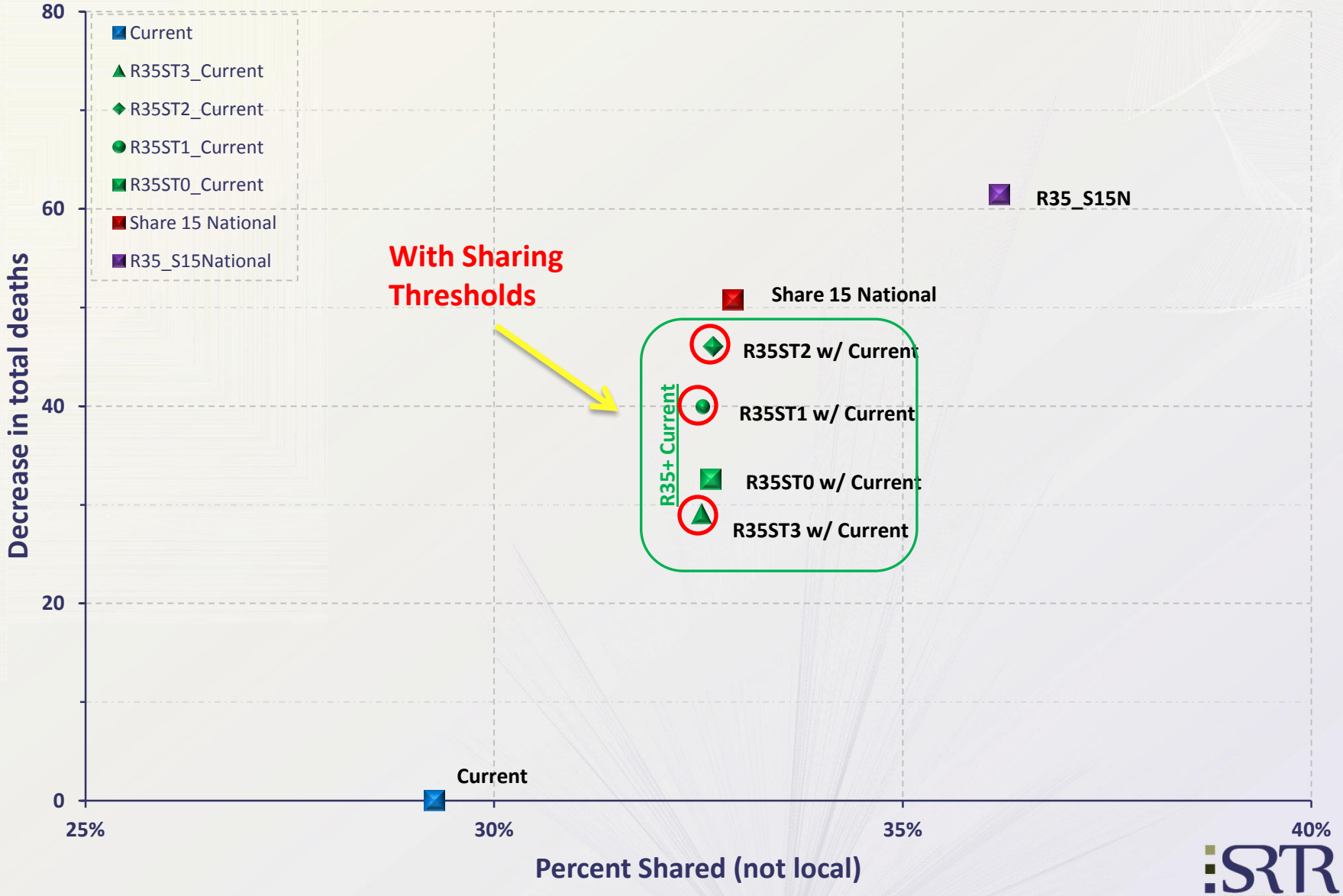
Organs 'Criss-crossing'

- Could incorporate a sharing threshold
  - Modeling data show ~5% of organs would be affected by a ST
  - Con:
    - Little change in waitlist death or with % shared with any level of ST
    - Difficult to explain
    - Complex algorithm
- Hard to predict center behavior
  - Types of livers that would be transported
  - Use of other teams to procure

Sharing Threshold

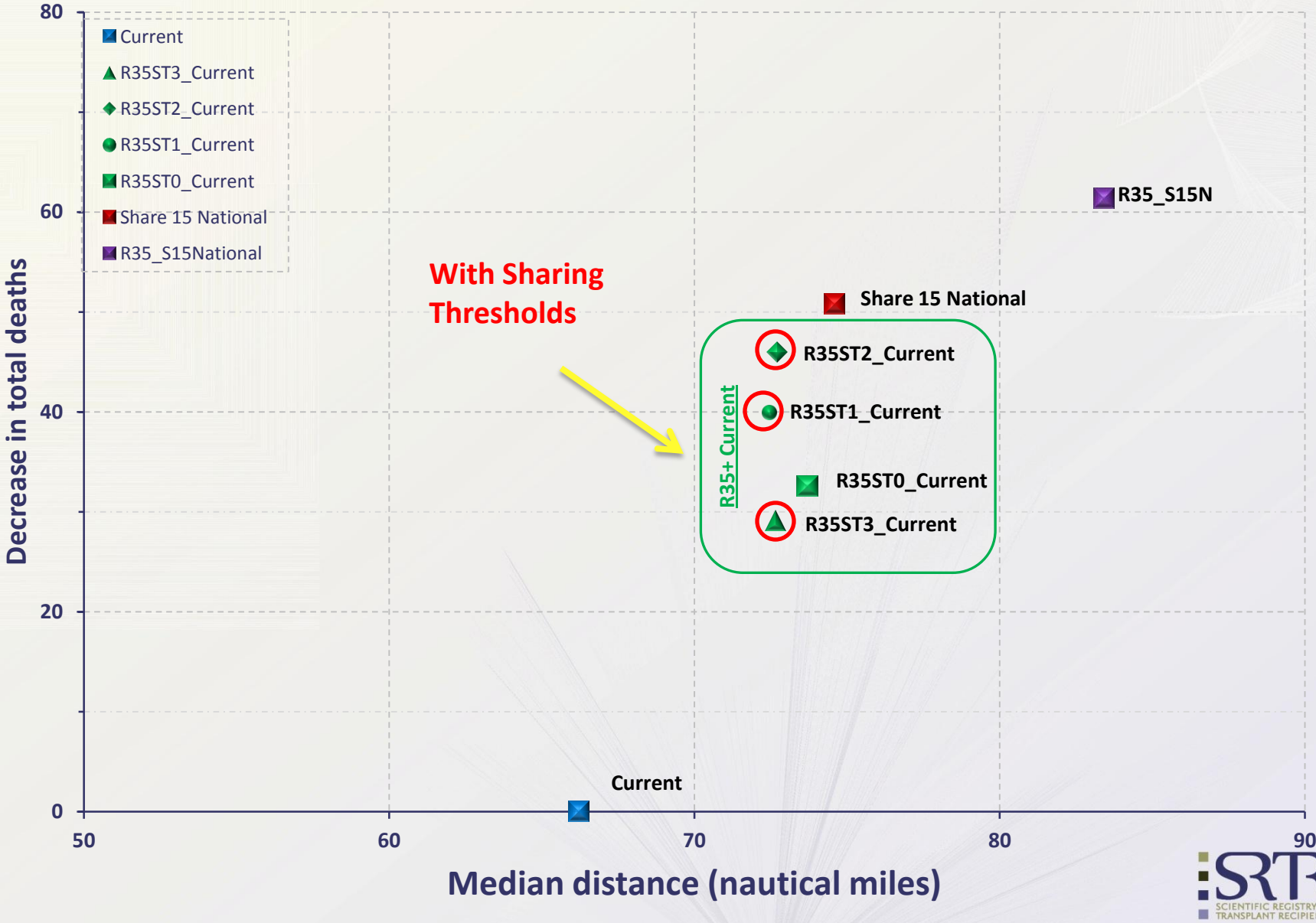


Decrease in Total Deaths vs. Percent Shared



SRTR
SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Decrease in Total Deaths vs. Median Distance



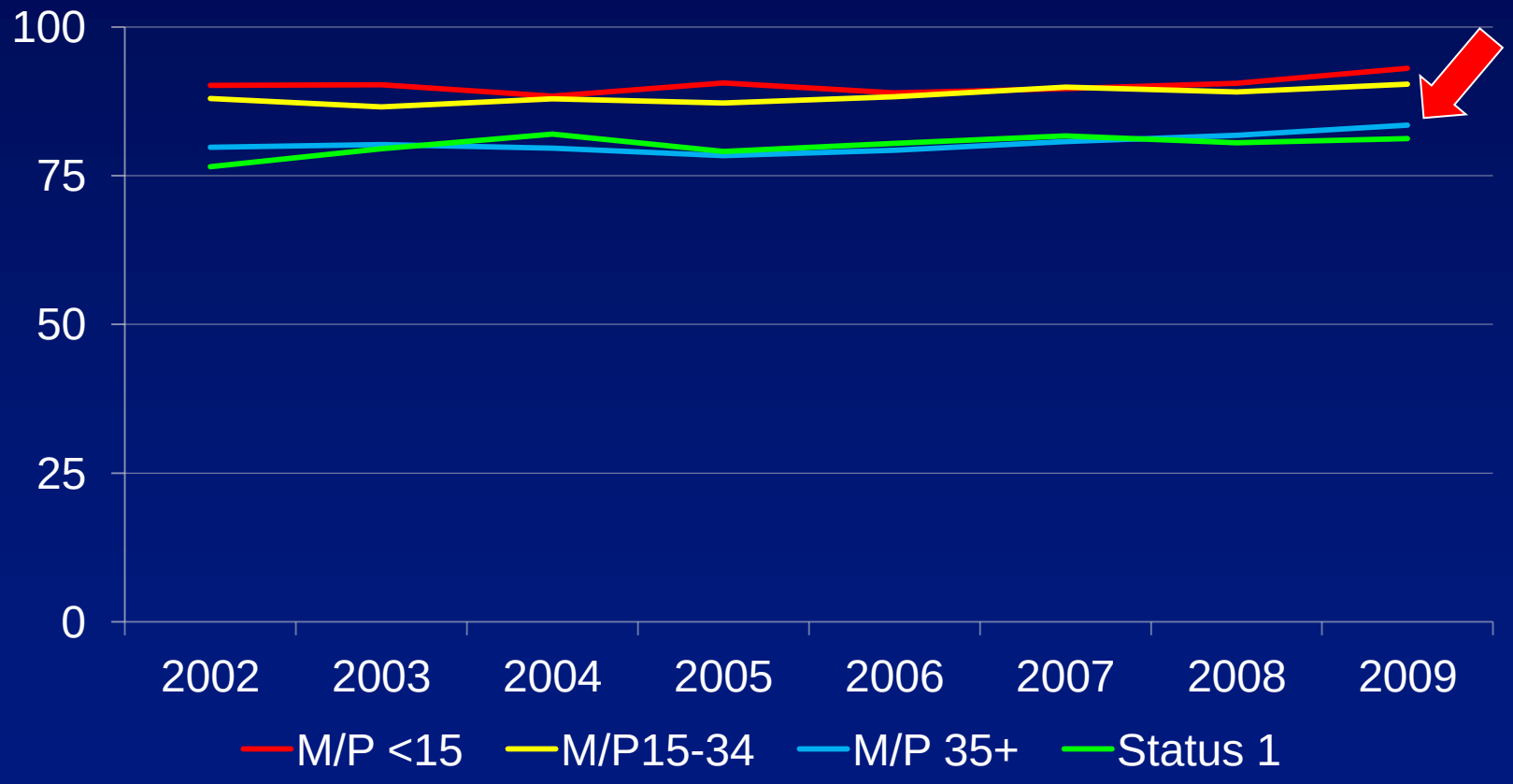
SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Cold Ischemia Time

- SRTR Data: Median CIT does not correlate well with distance
  - Range: 6 hours for very short distances to 7 hours for > 250 miles

Potential worse outcomes

1-Year Post-Transplant
Patient Survival Rates by MELD
Organ: Deceased Donor Liver



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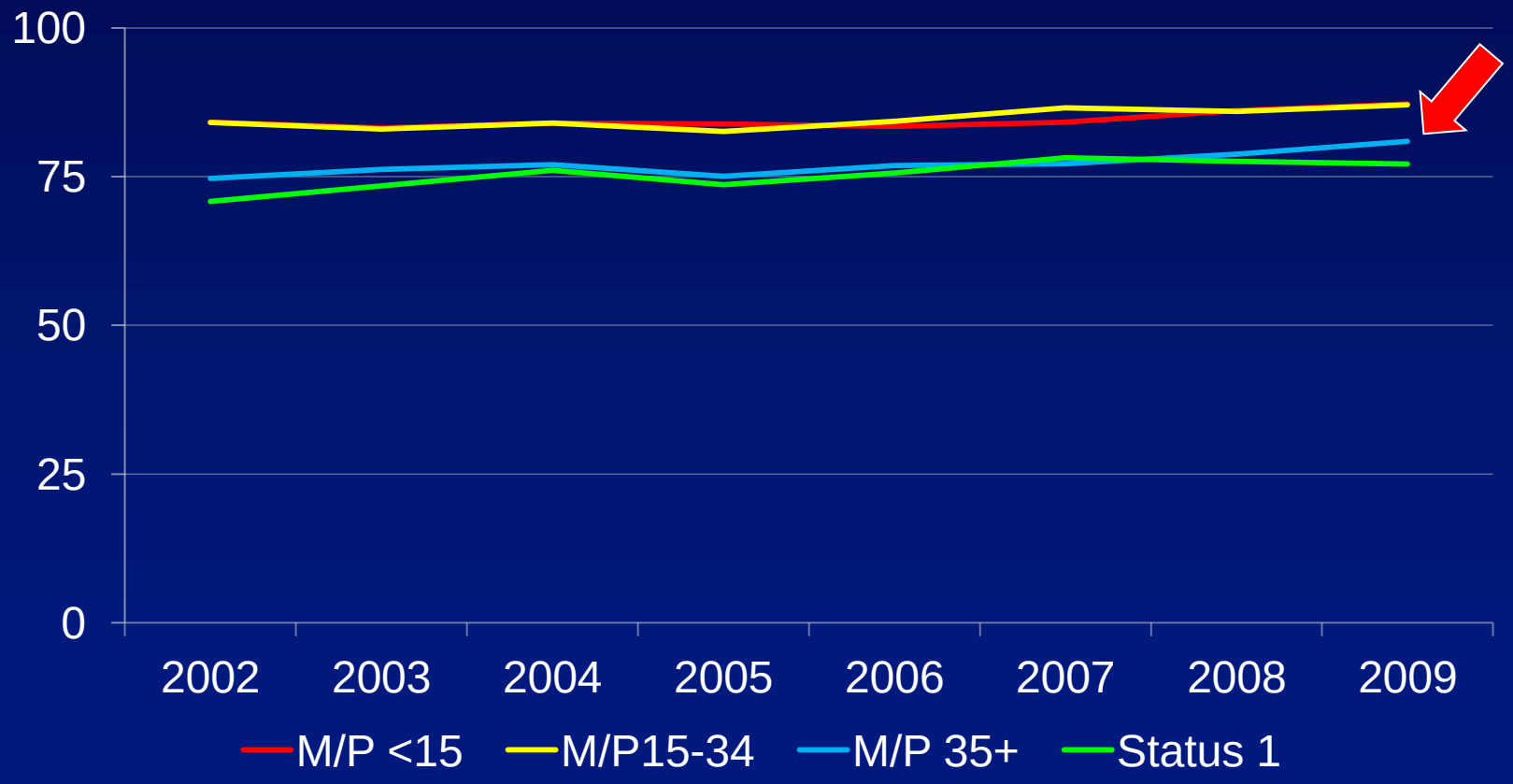
Potential worse outcomes

1-Year Post-Transplant
Graft Survival Rates by MELD
Organ: Deceased Donor Liver



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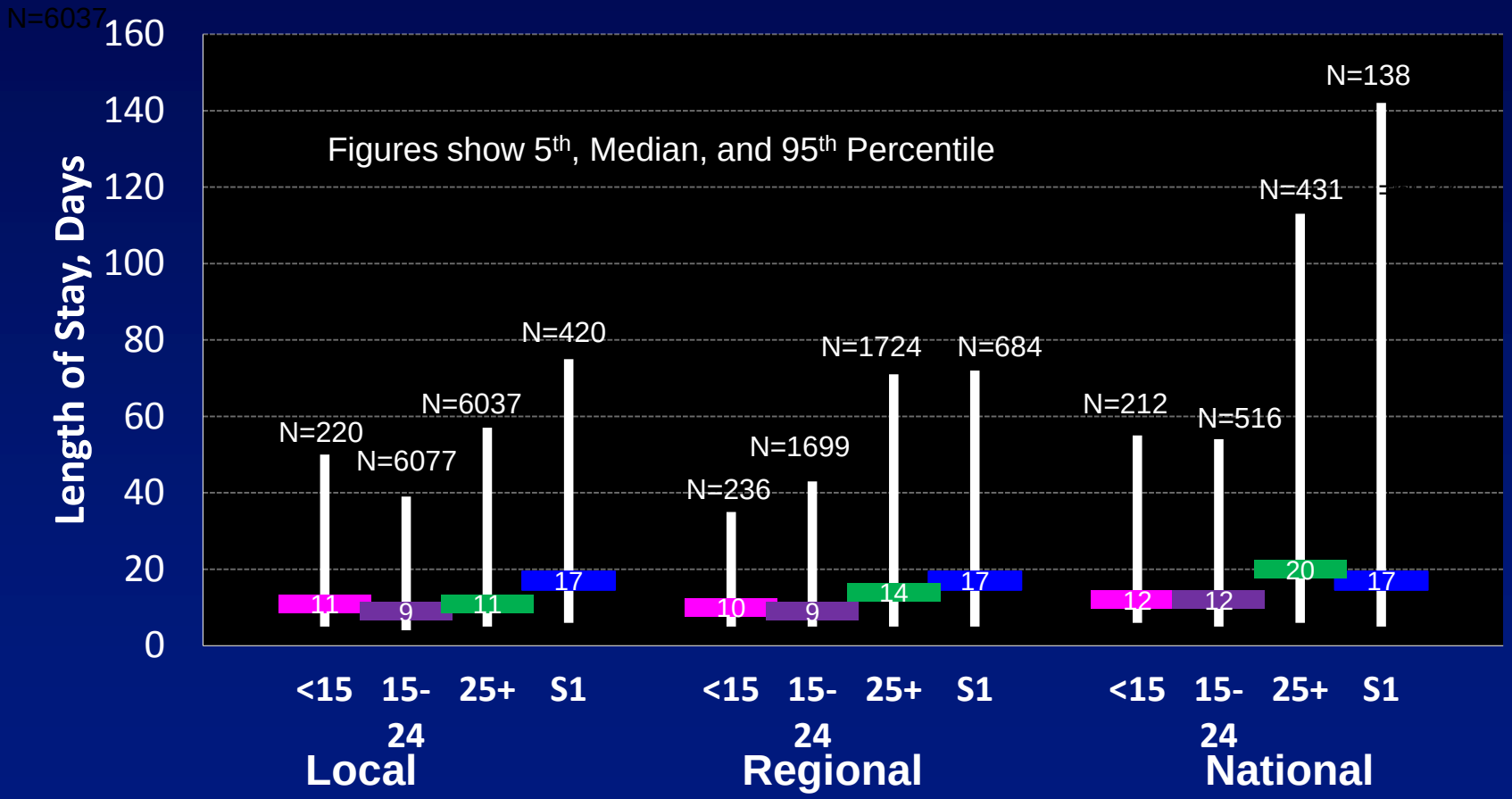
Distribution of Length of Stay for Local, Regional, National Shares Deceased Donor Liver Transplants 2007-2009



Status 1A/1B or MELD/PELD Category

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Potential Increased Cost

Axelrod, et al, AJT 2011

- *Simulation analysis of reallocation of livers from low MELD patients to high MELD using two-tiered regional sharing approach (MELD 15/25) resulted in 88 fewer deaths annually at estimated cost of $17,056 per quality-adjusted life-year saved.*
- *Results suggest broader sharing of liver allografts offers a cost-effective strategy to reduce mortality from end stage liver disease.*

Potential Increased Cost (Cont'd)

Axelrod, ATC, 2011

- Broader sharing may reduce cost of care for patients with ESLD
  - Reduced number of high MELD patients
  - More appropriate use of high DRI organs

Impact on Donation

- Often cited by opponents of broader distribution
- Volk, et al, AJT 2010 – probability-based national sample of adults aged ≥18

  Only 10% of participants indicated that organs should stay in the community where they are donated, whereas the remainder of participants supported sharing of organs between communities."

Why not share at M/P 29 or 32?

- Committee felt it would not be supported by consensus of community
  - Some surveyed supported broader than 29
  - Data supports equivalent waitlist death for 35+ compared to Status 1
  - No similar data for MELD < 35

Other Limitations

- Limited by 2010 Appropriations Bill Conference Report Language
  - "Any policy change on broader allocation of livers be tested first in demonstrations…"
  - OPTN plans to comply with report requests
  - Only "Demonstration" for a Regional Share: Region 8 AAS (Share 29)
    - Under-powered to demonstrate significance, although waitlist deaths were decreased by 6%
  - Share 15 Demonstrated in Every Region

Plan for Evaluating: Share 15N

Data will be reviewed every 6 months post-implementation. This will include:

- Waitlist mortality by MELD score
- Post-transplant patient and graft survival
- Percent shared between OPOs
- Percent shared nationally

Plan for Evaluating: Share 35R

Data will be reviewed every 6 months post-implementation. This will include:

- Waitlist mortality by MELD score
- Post-transplant patient and graft survival
- Percent shared between OPOs
- Percent shared nationally
- Percent of MELD exceptions scores transplanted at high MELDs (35+)

Additional Information

Additional Data Collection:

These proposals do not require additional data collection (forms) in Tiedi[SM]

Expected Implementation Plan:

UNOS Information Technology (IT) staff will need to reprogram UNet[SM] to implement these algorithms

Questions?